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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/925,728  | 08/10/2001  | Peter Geistlich      | 1194-179            | 5552             |
| 6449  | 7590        | 04/08/2005           | EXAMINER            |                  |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C.<br>1425 K STREET, N.W.<br>SUITE 800<br>WASHINGTON, DC 20005 |             |                      | PELLEGRINO, BRIAN E |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3738                |                  |

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                       |   |  |
|------------------------------|---------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/925,728  | <b>Applicant(s)</b><br>GEISTLICH ET AL. |  |
|                              | <b>Examiner</b><br>Brian E Pellegrino | <b>Art Unit</b><br>3738                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 13-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-20 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/1/05 has been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6,10,15,16,18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abdul-Malak (5567806) in view of Stone et al. (5624463). Abdul-Malak et al. disclose a method of *promoting tissue regeneration* through the use of a collagen membrane that can be sutured at the site of repair, col. 2, lines 5-8. Abdul-Malak also discloses that a multilayer membrane having different layers of collagen can be used in the method and can be crosslinked, col. 2, lines 37-40,64-67. Abdul-Malak additionally discloses that the collagen membrane can be impregnated with glycosaminoglycan, col. 2, lines 58-60. Abdul-Malak disclose that the collagen used can be collagen I or III, col. 2, lines 28,29. Abdul-Malak additionally disclose that the glycosaminoglycan used can be hyaluronic acid, col. 3, lines 1-5. It can be construed

Art Unit: 3738

that Abdul-Malak disclose a matrix layer is oriented toward the damaged area since the membrane is a texture, i.e. "sponge-like" for tissue ingrowth, col. 2, lines 41-44, col. 6, lines 5-9. However, Abdul-Malak et al. do not disclose using collagen II as one of the layers in joint repair or that bonding can be used to fix the membrane at the site or to use cartilage cells, such as chondrocytes with the membrane. Stone shows (Fig. 9) a barrier layer 12 oriented away from the damaged area in a cavity of a joint and can be made predominately of collagen I, col. 7, lines 56,57. It can also be interpreted that the barrier layer 12 has a fibrous face and smooth face as shown (Fig. 9) for adhering to the inner material, col. 9, lines 62,63, col. 10, lines 1,2. The examiner is interpreting the claimed elements "barrier layer" in this way: since the outer material of Stone is a boundary, it can be construed as a barrier layer. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Stone also shows the multi-component patch device has the inner component with an open sponge-like texture, Fig. 4B. Stone et al. additionally teaches the inner material is also made of collagen and can be collagen II, col. 9, lines 33-35, col. 12, lines 54-56. Stone teaches the patch or device is fixed to the area of treatment by adhesively bonding to the area, col. 5, lines 41-43. Biologically active substances, such as chondrocytes are charged into the patch, col. 15, lines 43-45. Stone also teaches that natural cartilage can be used from pigs to obtain collagen II (inherently hyaline type), col. 8, lines 62,63. It would have been obvious to one of ordinary skill in the art to substitute collagen II with chondrocytes as taught by Stone in the membrane of Abdul-Malak such that it provides

a natural material present in the area that it is used for, such as collagen II (commonly present in cartilage). Regarding the thickness limitations, it would have been an obvious matter of design choice to modify the thickness of the barrier layer or matrix layer, since applicant has not disclosed that using the specific thickness for each layer provide any advantage, or solve a stated problem, or are chosen for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thickness of the layers taught by Abdul-Malak or the claimed 0.2-2mm for the barrier layer or the 0.2-12mm for the matrix layer in claim(s) 1 because both membranes perform the same function of utilizing collagen as the repair material.

Claims 7,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abdul-Malak '806 in view of Stone et al. '463 as applied to claims 1,6 above, and further in view of Geistlich et al. (WO 95/18638). Abdul-Malak as modified by Stone et al. is explained supra. However, Abdul-Malak in view of Stone et al. do not disclose a pharmaceutical, such as taurolidine and that the membrane material is taken from the peritoneum. Geistlich teaches that chemotherapeutics can be used such as taurolidine with a membrane in cartilage repair, page 11, lines 7-10. Geistlich also teaches the membrane material can be obtained from the peritoneal membranes of calves, page 12. It would have been obvious to one of ordinary skill in the art to use taurolidine or peritoneal material as taught by Geistlich with the method and device of Abdul-Malak as modified by Stone such that it therapeutically treats the patient and is from a biological source.

Claims 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abdul-Malak '806 in view of Stone et al. '463 as applied to claim 6 above, and further in view of Sonis (WO 90/13302). Abdul-Malak as modified by Stone et al. is explained supra. However, Abdul-Malak in view of Stone et al. do not disclose the membrane carrying pharmaceutically active substances, such as BMPs. Sonis teaches that BMPs can be used with membranes for tissue regeneration, page 10, lines 22-31. Table II (page 28) show numerous agents, i.e. PDGF or PTH. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with a pharmaceutically active substance as taught by Sonis in the membrane of Abdul as modified by Stone in order to enhance the capabilities of the tissue regeneration process and allow for controlled release of the substances.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abdul-Malak '806 in view of Stone et al. '463 as applied to claim 1 above, and further in view of Caplan et al. (5197985). Abdul-Malak in view of Stone et al. is explained supra. However, Abdul as modified by Stone et al. do not disclose the use of bone marrow stromal cells incorporated in the membrane. Caplan et al. teach that bone marrow cells can be incorporated into carriers or membranes for tissue regeneration, col. 2, lines 6-11,27-34. Caplan also teaches that the stem cells are capable of determining which connective tissue to regenerate, i.e. cartilage, col. 3, lines 20-24,35-45. The cells and carrier is used to repair cartilage of a joint, col. 16, lines 40-53. Caplan additionally teaches that stromal cells from bone marrow can be harvested for use, col. 15, lines 25-28,39-49. It would have been obvious to one of ordinary skill in the art to impregnate

Art Unit: 3738

the membrane with stromal cells as taught by Caplan et al. in the membrane of Abdul in view of Stone et al. in order to provide enhanced osteogenic activity.

Claims 13,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malak '806 in view of Stone et al. '463 as applied to claim 1 above, and further in view of Geistlich et al. (5573771). Abdul-Malak as modified by Stone et al. is explained supra. However, Abdul in view Stone et al. do not disclose the use of a bone mineral implanted in the region of the bone injury. Geistlich et al. '771 teach that a bone mineral is useful for implanting in a bone cavity for remodeling, col. 2, lines 52-62. Geistlich '771 also teaches the bone mineral improves strength of the bone at the defect and these implants can be charged with bone cells, col. 3, lines 10-15,53-56. It would have been obvious to one of ordinary skill in the art to use a bone mineral as taught by Geistlich et al. '771 charged with the chondrocytes in the membrane of Abdul in view of Stone in order strengthen the area of the defect and provide a more natural environment for the cells.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malak '806 in view of Stone et al. '463 as applied to claim 1 above, and further in view of Seid (5254133). Abdul as modified by Stone et al. is explained supra. However, Abdul in view Stone do not disclose the use of two barrier layers to sandwich the matrix. Seid teaches (Fig. 13) that a coating **76** forms a barrier layer that sandwiches an inner component of the tissue patch. Seid also teaches the coating prevents tissue formation, col. 9, lines 3-8. It would have been obvious to one of ordinary skill in the art to use a

barrier layer on both sides of the matrix of Abdul as modified by Stone using the teaching of Seid to inhibit tissue formation prematurely.

### ***Response to Arguments***

Applicant's arguments filed 1/10/05 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The combination suggests that the a matrix structure in the form of sheet of collagen material is placed over a damaged area because the base reference (Abdul) discloses orienting the membrane toward the damaged area to allow ingrowth, col. 6, lines 5-9. The teaching reference provides the use of collagen II as the inner material and placing a barrier material with a fibrous face toward the inner material, col. 12, lines 54-56. Applicant contends the outer layer taught by Stone is termed a matrix, but fails to acknowledge that the examiner is not relying on what Stone nominally names the layers, but its structural characteristics. A claim term used contrary to its ordinary meaning, must be clearly redefined in the written description to set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Since the outer material of Stone is a boundary, it can be construed as a barrier layer.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (571) 272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

*Brian E. Pellegrino*